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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/668,119	09/22/2000	William B. Solomon	011.00250	9568

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EXAMINER

MARVICH, MARIA

ART UNIT PAPER NUMBER

1636

DATE MAILED: 11/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/668,119

Applicant(s)

SOLOMON ET AL.

Examiner

Maria B Marvich, PhD

Art Unit

1636

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

THE REPLY FILED 25 September 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 25 September 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see #10 below. Add

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1-7, 13-17 and 23.

Claim(s) withdrawn from consideration: 18-22 and 25-36.

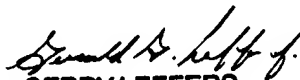
8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☒ Other: See Continuation Sheet

Continuation of 5. does NOT place the application in condition for allowance because: The claims, if amended as proposed, would not avoid the rejection under 35 U.S.C. § 101 set forth in the last office actions, and thus the amendment would not place the case in condition for allowance or in better condition for appeal.

Continuation of 10. Other: According to the revised amendment format, if the amendment adds, changes, or deletes any claim, a listing of all claims that are or were in the application must include the text for all claims under examination; however, no text for "withdrawn" claims should appear in the listing of claims. In the instant case, claims 18-22 and 25-36 are withdrawn therefore, no text should accompany these claims. As the amendment does not meet the revised amendment format, the amendment will not be entered.

Applicants traverse the claim rejections on pages 7-8 of the amendment filed 9/25/03. Applicants argue that the specification discloses a utility for the recited protein and corresponding nucleotide sequence. The disclosure teaches that the protein(s) have transcriptional activation activity (page 15, line 17-18) and provide some evidence that the protein "may have transcriptional regulatory activity when tethered to DNA" (page 28, line 7-18). Applicants argue that evidence that the protein is a transcriptional regulatory protein is found in the specification on page 41, line 29 through page 43 line 14. In experiments presented in these pages, TIG-1 is associated with TPA induction of CAT activity. Applicants argue that they must provide only one credible asserted utility in order to meet the criteria for 35 U.S.C. § 101.

Applicant's arguments filed 9/25/03 have been fully considered but they are not persuasive. Applicants have cloned TIG-1 from an EST library from TPA-induced K562 cells. Applicants have hypothesized that TIG-1 can behave as a transcriptional activator due to the effect of GAL4-TIG-1 on CAT reporter expression in K562 cells. While this protein has no DNA binding domain, it is further hypothesized that TIG-1 may function as a transcriptional regulatory protein. However, applicants have not provided a substantial and specific utility for the claimed polypeptide and nucleotide sequence of TIG-1. While applicants argue that they must provide only one credible asserted utility in order to meet the criteria for 35 U.S.C. § 101, the rejection was not made on the grounds of any and all of the asserted utilities as being incredible (e.g. in the sense of a perpetual motion machine). The grounds of rejection were made on the basis of a lack of a substantial and specific utility. That the protein may be a transcriptional regulatory factor does not provide a specific benefit in currently available form, and therefore the recited claims lack the substantial utility required by 35 U.S.C. § 101.


GERRY LEFFERS
PRIMARY EXAMINER